Complete Summary

GUIDELINE TITLE

Antibiotic prophylaxis in spine surgery.

BIBLIOGRAPHIC SOURCE(S)

Watters WC III, Baisden J, Bono C, Heggeness M, Resnick D, Shaffer WO, Toton J. Antibiotic prophylaxis in spine surgery. Burr Ridge (IL): North American Spine Society (NASS); 2007. 84 p. [104 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Surgical site infections associated with open spine surgery

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Neurological Surgery
Orthopedic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations to address key clinical questions surrounding the use of prophylactic antibiotics in spine surgery
- To assist in delivering optimum, efficacious treatment with the goal of preventing surgical infection
- To assist spine surgeons in preventing surgical site infections

TARGET POPULATION

Adults (18 years or older) undergoing spine surgery

INTERVENTIONS AND PRACTICES CONSIDERED

Antibiotic prophylaxis for spine surgery

MAJOR OUTCOMES CONSIDERED

Incidence of postoperative infection in patients undergoing spine surgery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The lists were compiled into a master list, which was then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, served to focus the guideline.

Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, North American Spine Society (NASS) has instituted a Literature Search Protocol (Appendix D in the original guideline document) which has been followed to identify literature for evaluation

in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the appendices (Appendix E in the original guideline document).

Completion of the Literature Search

After each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history in EndNote,™ for future use or reference.

Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they would review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members identified the best research evidence available to answer the targeted clinical questions. That is, if Level I, II and/or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

The North American Spine Society Literature Search Protocol used to identify literature for development of this guideline can be found in Appendix D 'Literature Search Parameters' of the original guideline document.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Primary Research Question[1]

Types of Studies

	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analys Developing an economic or dec model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review[2] of Level I RCTs (and study results were homogenou[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible and alternati values obtained many stu with mul sensitivit analyses • Systema review[2] Level I st
Level II	• Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible and alternati values obtained limited studies; multiway sensitivit analyses • Systema review[2] Level II studies

Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of nonconsecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternati and costs and poor estimate • Systema review[2] o Level III studies
Level IV	Case series[8]	Case series	• Case-control study • Poor reference standard	Analyses with n sensitivity analy
Level V	Expert opinion	Expert opinion	Expert opinion	Expert opinion

RCT = randomized controlled trial.

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called "cases"; e.g., failed total arthroplasty, are compared to those who did not have outcome, called "controls"; e.g., successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evidence Analysis

Members of the work group independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members reviewed each article selected and independently assigned levels of evidence to the literature using the North American Spine Society levels of evidence. Any discrepancies in scoring have been

addressed by two or more reviewers. The consensus level (the level upon which two thirds of reviewers were in agreement) was then assigned to the article.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Nominal Group Technique)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because North American Spine Society (NASS) is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross-section of NASS membership is represented on each group whenever feasible. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held Webcasts to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate"). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, work group members developed the guideline content, addressing the literature which supports the recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

A: Good evidence (Level I studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence-based Guideline Development Committee, the Clinical Care Council Director and the Advisory Panel for review and comment. The Advisory Panel is comprised of representatives from physical medicine and rehab, pain medicine/management, orthopedic surgery, neurosurgery, anesthesiology, rheumatology, psychology/psychiatry and family practice. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Submission for Board Approval

After any evidence-based revisions were incorporated, the drafts were prepared for North American Spine Society (NASS) Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

This guideline will be pilot-tested among spine care specialists and primary care physicians for one year following publication. Findings of the pilot test will be considered to inform future guideline development.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of recommendations (A-C, I) and levels of evidence (I-V) are defined at the end of the "Major Recommendations" field.

Recommendations Regarding Antibiotic Prophylaxis in Spine Surgery

Efficacy

For patients undergoing spine surgery, does antibiotic prophylaxis result in decreased infection rates compared to patients who do not receive prophylaxis?

Patients undergoing spine surgery should receive preoperative prophylactic antibiotics.

Grade of Recommendation: B

For patients undergoing spine surgery *without* spinal implants, does antibiotic prophylaxis result in decreased infection rates as compared to patients who do not receive prophylaxis?

Prophylactic antibiotics are recommended to decrease the rate of spinal infections following uninstrumented lumbar spinal surgery.

Grade of Recommendation: B

For patients undergoing spine surgery *with* spinal implants, does antibiotic prophylaxis result in decreased infection rates as compared to patients who do not receive prophylaxis?

Prophylactic antibiotics are recommended to decrease the rate of infections following instrumented spine fusion.

Grade of Recommendation: C

Protocol

For patients receiving antibiotic prophylaxis prior to spine surgery, what are the recommended drugs, their dosages and time of administration resulting in decreased postoperative infection rates?

Patients undergoing spine surgery should receive preoperative prophylactic antibiotics to decrease infection rates. The superiority of one agent or schedule over any other has not been clearly demonstrated.

Grade of Recommendation: B

For patients receiving antibiotic prophylaxis prior to spine surgery *without* spinal implants, what are the recommended drugs, their dosages and time of administration resulting in decreased postoperative infections rates?

Review of the current literature does not allow recommendation of one specific antibiotic protocol or dosing regimen over another in the prevention of postoperative infections following uninstrumented spinal surgery.

Level of Evidence: II

For patients receiving antibiotic prophylaxis prior to spine surgery *with* spinal implants, what are the recommended drugs, their dosages and time of administration resulting in decreased postoperative infections rates?

In patients with risk factors for polymicrobial infection, it is recommended that appropriate broad spectrum antibiotics be considered when instrumented fusion is performed.

Grade of Recommendation: C

Redosing

For patients receiving antibiotic prophylaxis prior to spine surgery, what are the intraoperative redosing recommendations for the recommended drugs (including dosages and time of administration) resulting in decreased postoperative infection rates?

Dosing regimens do not appear to affect infection rates. Although no study has shown any significant advantage to intraoperative redosing compared with a single dose, specific clinical situations may dictate additional doses (e.g., length of surgery, comorbidities).

Level of Evidence: IV

Discontinuation

For patients receiving antibiotic prophylaxis prior to spine surgery, does discontinuation of prophylaxis at 24 hours result in decreased or increased postoperative infection rates as compared to longer periods of administration?

A comprehensive review of the spine literature did not yield evidence to address the question related to the effect on postoperative infection rates of discontinuation of prophylaxis at 24 hours compared with longer periods of administration.

Wound Drains

For patients receiving antibiotic prophylaxis prior to spine surgery and who receive placement of wound drains at wound closure, does discontinuation of prophylaxis at 24 hours result in decreased or increased postoperative infection rates as compared to discontinuation of antibiotics at time of drain removal?

A comprehensive review of the literature did not yield evidence to address the question related to the effect on postoperative infection rates of the duration of prophylaxis in the presence of a wound drain.

The use of drains is not recommended as a means to reduce infection rates following single level surgical procedures.

Grade of Recommendation: I (Insufficient Evidence)

Body Habitus

For patients receiving antibiotic prophylaxis prior to spine surgery, should the recommended protocol differ based upon body habitus (e.g., body mass index)?

Obese patients are at higher risk for postoperative infection, when given a standardized dose of antibiotic prophylaxis. In spite of this conclusion, the literature search did not yield sufficient evidence to recommend any specific modifications to antibiotic protocols for this specific population.

Level of Evidence: III

Comorbidities

For patients receiving antibiotic prophylaxis prior to spine surgery, do comorbidities (other than obesity) such as diabetes, smoking, nutritional depletion and immunodeficiencies alter the recommendations for antibiotic prophylaxis?

Based on the literature reviewed to address this question, information was only available on patients with diabetes, older age or instrumentation. While this information suggests that these three groups are at higher risk for postoperative infection when given a standardized dose of antibiotic prophylaxis, the literature search did not yield sufficient evidence to recommend any specific modifications to antibiotic protocols for this specific population.

Level of Evidence: III

Definitions:

Levels of Evidence for Primary Research Question[1]

	Types of Studies			
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of antibiotic prophylaxis in spine surgery for prevention of surgical site infections

POTENTIAL HARMS

Obese patients are at higher risk for postoperative infection, when given a standardized dose of antibiotic prophylaxis.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline does not represent a "standard of care," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and doctor's professional judgment. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.
- This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Watters WC III, Baisden J, Bono C, Heggeness M, Resnick D, Shaffer WO, Toton J. Antibiotic prophylaxis in spine surgery. Burr Ridge (IL): North American Spine Society (NASS); 2007. 84 p. [104 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Jan

GUIDELINE DEVELOPER(S)

North American Spine Society - Medical Specialty Society

SOURCE(S) OF FUNDING

North American Spine Society (NASS)

GUIDELINE COMMITTEE

North American Spine Society (NASS) Evidence Based Guideline Development Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: William C. Watters III, MD, Committee Chair; Jamie Baisden, MD; Christopher Bono, MD; Michael Heggeness, MD, PhD; Daniel Resnick, MD; William O. Shaffer, MD; John Toton, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues and their potential conflicts have been documented for future reference. They will not be published in any guideline, but kept on file for reference, if needed. Participants have been asked to update their disclosures regularly throughout the guideline development process

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the North American Spine Society Web site.

Print copies: Available from the North American Spine Society (NASS), 7075 Veterans Boulevard, Burr Ridge, IL 60527; Toll-free: (866) 960-6277. An order form is available from the North American Spine Society Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on April 21, 2008. The information was verified by the guideline developer on June 6, 2008.

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